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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,196	06/19/2001	Richard S. Blumberg	G0694/7002 (JRV)	5225

23628 7590 07/29/2003

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EXAMINER
VANDERVEGT, FRANCOIS P

ART UNIT	PAPER NUMBER
1644	10

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/884,196	Applicant(s) BLUMBERG, RICHARD S.
	Examiner F. Pierre VanderVegt	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-18,40-48 and 57-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-18, 40-48 and 57-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9, 10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The Examiner in charge of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to F. Pierre VanderVegt, Ph.D. in Art Unit 1644.

This application is a divisional of U.S. Application Serial Number 09/293,504, which claims the benefit of the filing date of provisional application 60/081,895.

Claims 1-9, 19-39 and 49-56 have been canceled previously.

Claims 57-62 were previously added.

Claims 10-18, 40-48 and 57-62 are currently pending.

Election/Restrictions

Applicant's election with traverse of the species "intestinal intraepithelial lymphocytes" in Paper No. 8, filed May 15, 2003, is acknowledged. The traversal is on the ground(s) that search for the elected species will reveal information relevant to the other species as well. This is not found persuasive because different types of T cells perform different functions in the immune response.

Upon further review, no claims are withdrawn from further consideration pursuant to 37 CFR 1.142(b).

Accordingly, **claims 10-18, 40-48 and 57-62 are the subject of examination** in the present Office Action.

Claim Rejections - 35 USC § 112

Claims 10-18, 40-48 and 57-62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific suppression of isolated killer T cells, does not reasonably provide enablement for specific suppression of killer T cells in a mixed population of cells or *in vivo*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claimed invention is drawn to specific suppression of killer T cells under any conditions (claims 40-48 and 60-62) or in a subject (claims 10-18 and 57-59) by contacting the killer T cells with an agent which increases the cross-linking of biliary glycoprotein (CD66a) selected from a monoclonal antibody or fragments of biliary glycoprotein). Watt et al (C42 on form PTO-1449) disclose that biliary

glycoprotein, disclosed as CEACAM1 (page 1469, column 1 in particular), is an adhesion molecule which is "expressed widely, occurring on monocytes, granulocytes and their precursors, activated T cells, and $CD16^{-}CD56^{+}$ natural killer cells, B cells and the epithelium and endothelium of a variety of tissues. It is notable that the instant specification concurs with this finding, disclosing the staining of a variety of tissues in several organs in Table 1 on page 26, for example. The instant specification only demonstrates the suppression of killer T cell activity in propagated killer T cell lines or in isolated killer cells that have been enriched post-isolation via in vitro stimulation. The specification does not show that any of the agents disclosed as being able to increase cross-linking of CD66 specifically on killer T cells in a mixed population of cells or in vivo. Given the disclosure of Watt regarding the wide expression of CD66 on various cells and tissues, one of skill in the art would not be able to reasonably predict that one would be able to selectively suppress the activity of killer T cells in either a mixed population of cells bearing the CD66 antigen or in vivo, where the CD66 antigen is also expressed on endothelial and epithelial tissues. Without additional guidance from the instant specification, the artisan would not be able to practice the claimed invention, which is to specifically suppress killer T cells, as the specification does not disclose how to specifically target said killer T cells by increasing the cross-linking of the biliary glycoprotein on said killer T cells without also increasing the cross-linking of biliary glycoprotein on other cell types which may be present in a mixture and would certainly be present in vivo. The specification does not adequately teach how to effectively reach any therapeutic endpoint in vivo by administering an agent which increases the cross-linking of biliary glycoprotein. The specification does not teach how to extrapolate data obtained from *in vitro* binding inhibition assays to the development of effective *in vivo* therapeutic compositions, commensurate in scope with the claimed invention. Therefore, it is not clear that the skilled artisan could predict the efficacy of the agent exemplified in the specification or the breadth of specific suppression of killer T cells, encompassed by the claims.

In view of the breadth of the claims, the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, and the lack of sufficient guidance in the specification, it would take undue trials and errors to practice the claimed invention.

Conclusion

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (703) 305-4441. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
July 28, 2003

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TECH CENTER 1600
7/28/03